



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2007-1080; FRL-9375-7]

Endocrine Disruptor Screening Program; Final Policies and Procedures for Screening Safe Drinking Water Act Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document describes EPA's final policies and procedures for requiring Tier 1 screening under the Endocrine Disruptor Screening Program (EDSP) of chemicals for which EPA may issue EDSP test orders pursuant to section 1457 of the Safe Drinking Water Act (SDWA) and section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 408(p) of the FFDCA directed EPA to develop a chemical screening program using appropriate validated test systems and other scientifically relevant information (OSRI) to determine whether certain chemicals may have hormonal effects. These final policies and procedures supplement the EDSP policies and procedures that were published in the **Federal Register** on April 15, 2009.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you produce, manufacture, use, or import chemicals (including pesticide chemicals) that may be found in sources of drinking water; if you manufacture or import chemicals that degrade to chemicals found in sources of drinking water; or if you are, or may otherwise be, involved in the testing of chemicals for potential endocrine effects. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical manufacturers, importers, and processors (NAICS code 325), e.g., persons who manufacture, import, or process chemicals.
- Pesticide, fertilizer, and other agricultural chemical manufacturers, importers, and processors (NAICS code 3253), e.g., persons who manufacture, import, or process pesticide; fertilizer; or agricultural chemicals.
- Scientific research and development services (NAICS code 5417), e.g., persons who conduct testing of chemicals for endocrine effects.

To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit III.C., and examine FFDCA section 408(p). If you have any questions regarding the applicability of this action to a particular entity, consult either technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2007-1080, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. Background

A. What Action is the Agency Taking?

The Agency is publishing final policies and procedures for issuing EDSP test orders for chemicals pursuant to the Agency's authority under SDWA section 1457 (i.e., "SDWA chemicals"). Section 1457 of the SDWA authorizes EPA to issue EDSP test orders to manufacturers and importers of chemicals that may be found in sources of drinking water and to which a substantial population may be exposed (42 USC 300j-17). SDWA chemicals encompass a wide variety of chemicals, including industrial and

pesticide chemicals, ingredients in pharmaceuticals and personal care products, and degradates.

These SDWA/FFDCA policies and procedures supplement the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)/FFDCA policies and procedures that were published in the **Federal Register** issue of April 15, 2009 (FIFRA/FFDCA policies and procedures) (Ref. 1). The FIFRA/FFDCA policies and procedures (Ref. 1) were developed primarily for the issuance of EDSP test orders on pesticide active and inert ingredients, which were the chemicals comprising the first EDSP chemical list (first list). Consequently, some of the FIFRA/FFDCA policies and procedures (Ref. 1) reflect issues uniquely associated with the pesticide market and the specific regulatory context under which EPA regulates pesticide chemicals. In this document, EPA describes the policies and procedures associated with the screening of SDWA chemicals, which include certain modifications to the FIFRA/FFDCA policies and procedures that are intended to address issues that are unique to SDWA chemicals, or to address the circumstances where other competing considerations for SDWA chemicals warrant a modification of the FIFRA/FFDCA policies and procedures.

This document discusses the policy considerations for SDWA chemicals in the following areas:

- Who would receive EDSP test orders for SDWA chemicals? Unit VI.A.
- How will recipients of EDSP test orders for SDWA chemicals be notified? Unit VI.B.
- How will the public know who has received an EDSP test order for a SDWA chemical or who has supplied data? Unit VI.C.

- How will the Agency minimize duplicative testing? Unit VI.D.
- What are the potential responses to EDSP test orders for SDWA chemicals?

Unit VI.E.

- How can an EDSP test order responses and data be submitted electronically?

Unit VI.F.

• How will EPA facilitate joint data development, cost sharing, and data compensation for SDWA chemicals? Unit VI.G.

• What procedures can EPA apply for handling Confidential Business Information (CBI) for SDWA chemicals? Unit VI.H.

• What is the process for contesting an EDSP test order or consequences for failure to respond or comply with an EDSP test order? Unit VI.I.

• What is the informal administrative review procedure? Unit VI.J.

• What are the adverse effects reporting requirements? Unit VI.K.

While the FIFRA/FFDCA policies and procedures (Ref. 1) remain relevant, SDWA chemical EDSP test order recipients are encouraged to refer to this document to fully understand all of the relevant policies and procedures. In addition, a new EDSP test order template for issuance of EDSP test orders under SDWA section 1457 and FFDCA section 408(p)(5) is available in the docket for this document (Ref. 2).

EPA is publishing two related notices elsewhere in this **Federal Register** issue. One announces the final second EDSP chemical list (second list), which includes both SDWA chemicals and pesticide active ingredients (PAIs). The other announces the submission to the Office of Management and Budget (OMB) of the final Information

Collection Request (ICR) Addendum that describes the estimated paperwork burden and costs associated with the second list.

B. What are the Statutory Authorities for the Policies Discussed in this Document?

SDWA is the primary Federal law that ensures the quality of Americans' drinking water. Under SDWA, EPA sets standards for drinking water and works closely with States, localities, and water suppliers to implement these standards. SDWA authorizes EPA to set national standards for drinking water to protect against both naturally occurring and man-made contaminants that may be found in drinking water (42 U.S.C. 300g-1).

Section 1457 of SDWA authorizes EPA to require testing, under FFDCA section 408(p) (21 U.S.C. 346(a)(p)), of any chemical that may be found in sources of drinking water if the EPA Administrator determines that a substantial population may be exposed to such chemical (42 U.S.C. 300j-17).

Section 408(p)(1) of FFDCA requires EPA "to develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effects as [EPA] may designate" (21 U.S.C. 346a(p)(1)).

Section 408(p)(3) of FFDCA expressly requires that EPA "shall provide for the testing of all pesticide chemicals" (21 U.S.C. 346a(p)(3)). Section 201 of FFDCA defines "pesticide chemical" as "any substance that is a pesticide within the meaning of [FIFRA], including all active and pesticide inert ingredients of such pesticide" (21 U.S.C. 231(q)(1)).

Section 408(p)(5)(A) of FFDCA provides that the EPA Administrator “shall issue an order to a registrant of a substance for which testing is required under [FFDCA section 408(p)], or to a person who manufactures or imports a substance for which testing is required under [FFDCA section 408(p)], to conduct testing in accordance with the screening program ..., and submit information obtained from the testing to the Administrator, within a reasonable time period that the [Agency] determines is sufficient for the generation of the information” (21 U.S.C. 346a(p)(5)(A)).

The statutes discussed in this unit provide EPA with the discretion to require testing of a pesticide chemical under FFDCA alone, or in any combination of the various authorities (e.g., FIFRA/FFDCA, SDWA/FFDCA, or FIFRA/SDWA/FFDCA).

Section 408(p)(5)(B) of FFDCA requires that, “to the extent practicable, the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information” (21 U.S.C. 346a (p)(5)(B)).

Section 408(p)(5)(D) of FFDCA provides that any person (other than a registrant) who fails to comply with a FFDCA section 408(p)(5) test order shall be liable for the same penalties and sanctions as are provided for under section 16 of the Toxic Substances Control Act (TSCA) (21 U.S.C. 346a (p)(5)(D)). Such penalties and sanctions shall be assessed and imposed in the same manner as provided in TSCA section 16. Under TSCA section 16, civil penalties of up to \$37,500 per day may be assessed, after notice and an administrative hearing held on the record in accordance with section 554 of the Administrative Procedure Act (APA) (15 U.S.C. 2615(a)(1)-(2)(A)).

In addition, Congress's House Appropriations Committee Report (H. Rept.) for EPA's FY 2010 appropriations (Ref. 3), directed EPA "to publish within 1 year of enactment a second list of no less than 100 chemicals for screening that includes drinking water contaminants, such as halogenated organic chemicals, dioxins, flame retardants (PBDEs, PCBs, PFCs), plastics (BPA), pharmaceuticals and personal care products, and issue 25 orders per year for the testing of these chemicals."

C. Does this Document Contain Binding Requirements?

While the requirements in the statutes and in any EDSP test orders ultimately issued under FFDCA section 408(p) are binding, the policies and procedures outlined in this document are not. The policies and procedures outlined in this document merely represent the general procedures and statutory interpretations on which EPA may rely to implement the existing goals of the statutory program. However, neither EPA nor any outside party is bound by any of the policies and procedures outlined in this document. Accordingly, these policies and procedures may be modified at any time by EPA and the Agency may depart from these policies and procedures where circumstances warrant and without prior notice.

III. Background on EDSP

A. What is EDSP?

EPA developed EDSP in response to a Congressional mandate in FFDCA "to determine whether certain substances may have an effect in humans that is similar to an effect produced by naturally occurring estrogen, or such other endocrine effect as [EPA] may designate" (21 U.S.C. 346a(p)). As part of EDSP, EPA issues orders to collect certain test data on selected chemicals. In general, EPA intends to use the data collected under EDSP, along with other information, to determine if a pesticide chemical, or other

chemicals, may pose a risk to human health or the environment due to disruption of the endocrine system. The determination of whether a chemical has the potential to interact with the endocrine system will be made on a weight of evidence basis taking into account data from the Tier 1 assays and/or OSRI. Chemicals that go through Tier 1 screening and are found to have the potential to interact with the estrogen, androgen, or thyroid hormone systems will proceed to the next stage of EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the chemical, and establish a quantitative relationship between the dose and that endocrine effect. Further information regarding EDSP and requirements for Tier 1 and Tier 2 can be found on the Agency's EDSP website (Ref. 4). EPA is aware of no issue specific to the chemicals in the second list that would warrant any modification to the existing testing scheme, and is not proposing to adopt any.

B. Why is EPA Publishing Additional Policies and Procedures for EDSP Tier 1 Screening?

As stated in the FIFRA/FFDCA policies and procedures (Ref. 1), EPA intended to develop EDSP policies and procedures that could be used in subsequent data collection efforts, including those under SDWA, but indicated that EPA may make modifications as appropriate. The Agency now believes that modifications are needed to address issues that are specific to the larger universe of chemicals that are potentially subject to EDSP testing under SDWA.

The FIFRA/FFDCA policies and procedures (Ref. 1) were originally developed for screening of pesticide chemicals and relied, in part, on a regulatory context that is specific to pesticide chemicals. The presumptions applicable in that context are not

necessarily applicable to this larger universe of chemicals.

For example, much of the data that would be generated in response to an EDSP test order (particularly for pesticide active ingredients) would be entitled to the data compensation protections available under FIFRA (7 U.S.C. 136a(c)(1)(F)) and FFDCA (21 U.S.C. 346a(i)). Additionally, FIFRA section 10 prohibits EPA from releasing study data on pesticide chemicals unless the person seeking access to the information certifies that he is not an agent or employee of any multinational pesticide company (7 U.S.C. 136h(g)). Because FFDCA section 408(p) did not authorize EPA to modify these FIFRA requirements, EPA needs to ensure that the policies and procedures adopted to implement FFDCA section 408(p) would operate in a manner that would be consistent with EPA's existing FIFRA mandates. Moreover, EPA could rely on the existing FIFRA mechanisms to effectively minimize duplicative testing, and to promote cost-sharing.

By contrast, these considerations are generally not applicable to the majority of chemicals that may be subject to EDSP screening under SDWA, such as chemicals used in pharmaceuticals and personal-care products, among others.

In addition, the statutory authority for imposing testing of SDWA chemicals, the sources of SDWA chemicals, and EPA's ability to identify manufacturers and importers, and other considerations unique to SDWA chemicals, create a need for policies and procedures specific to EDSP screening under SDWA/FFDCA authority. For example, some registered pesticide ingredients have additional uses that account for a much larger percentage of total manufacture and import. In such cases, the Agency seeks to be able to identify, and issue orders to, all relevant manufacturers and importers in a manner that creates a fair and level playing field for complying with the order.

C. When Do These Policies and Procedures Apply?

EPA has the discretion to issue EDSP test orders under the authorities of SDWA section 1457 and FFDCA section 408(p) for all chemicals, including PAIs, for which the Agency can make the requisite factual findings. As described in this document, however, EPA generally intends to use SDWA authority to require EDSP testing of SDWA chemicals that are not PAIs and FIFRA authority to require EDSP testing of PAIs and pesticide inerts, even if the PAIs and inerts have non-pesticide uses. EPA may issue SDWA/FFDCA EDSP test orders for PAIs and inerts that have non-pesticide uses, except, when PAI registrants avoid EDSP testing by canceling their registrations and leaving the market. This approach will preserve familiar data compensation and confidentiality protections established in FIFRA sections 3(c)(1)(F) and 12, as well as FFDCA section 408(i), for pesticide registrants.

IV. EDSP Policies and Procedures Considerations for SDWA Chemicals

The Agency used the following policies and procedures considerations to guide development of policies and procedures for issuing Tier 1 EDSP test orders on SDWA chemicals:

- A core part of EPA's mission is to promote public understanding of the potential risks posed by chemicals in commerce.
- The basis for an order with respect to SDWA chemicals is that a chemical may be found in sources of drinking water and a determination that a substantial population may be exposed to such chemical. Thus, SDWA/FFDCA policies and procedures should not be unnecessarily tied to the use of the chemical in any given market and should

instead focus on obtaining data from companies that might be expected to contribute to a chemical's presence in drinking water.

- For simplicity, policies and procedures for SDWA chemicals should be consistent with FIFRA/FFDCA policies and procedures (Ref. 1) unless there is a reason for modifying them (e.g., different statutory requirements), though for clarity EPA has written these SDWA/FFDCA policies and procedures as a complete, stand alone document.

- Procedures for EDSP testing of SDWA chemicals should strive to minimize duplicative testing and promote fair and equitable sharing of test costs, as described in FFDCA section 408(p)(5)(B).

- The Agency expects to issue SDWA/FFDCA EDSP test orders for pesticide inert ingredients that are listed for EDSP screening with a SDWA section 1457 finding; it has also been the Agency's experience that pesticide inerts generally have a much larger market than solely as ingredients in pesticide formulations. For these reasons EPA believes it is reasonable and equitable to initially issue SDWA/FFDCA EDSP test orders on SDWA chemicals that are not PAIs.

- As noted previously, EPA intends to require EDSP testing pursuant to FIFRA and FFDCA for registrants of a pesticide chemical, even if the chemical has non-pesticide uses. If, however, recipients of such EDSP test orders fail to provide the required information by dropping out of the pesticide market to avoid EDSP testing, EPA may choose to reissue EDSP test orders under SDWA/FFDCA authority if the SDWA criteria are met. EPA would then rely on the policies and procedures established in this document.

V. Discussion of Final SDWA/FFDCA Policies and Procedures and Response to Comments

This document adopts the proposed SDWA/FFDCA policies and procedures published in the **Federal Register** issue of November 17, 2010 (Ref. 5), with minor revisions. The Agency reviewed and considered all of the comments that were received on the proposed SDWA/FFDCA policies and procedures. All of the comments received are available in the docket for this document, and a response-to-comments document (Ref. 6) that summarizes and responds to all of the comments received on the proposed SDWA/FFDCA policies and procedures is also available in the same docket. The Agency specifically requested comments on five topics: Response option to cease manufacture; persistence; catch-up orders and data compensation; orphan chemicals; and electronic notification. The Agency's consideration of such comments is described in this unit and the Agency's response to comments document (Ref. 6).

A. Response Option to Cease Manufacture

EPA sought comment on whether a company could satisfy the EDSP test order simply by committing to stop manufacturing or importing a SDWA chemical, because, in ceasing to manufacture the chemical, the company thereby stops contributing to the presence of the chemical in the source of drinking water and reduces potential exposure. Alternatively, EPA sought comment on whether the company should be required to conduct the EDSP testing nevertheless, on the grounds that the company should not be able to evade responsibility for providing the data necessary to evaluate the existing water contamination to which their manufacturing activities had contributed.

Multiple commenters (the American Petroleum Institute (API), the American Chemistry Council (ACC), Bayer CropScience LP (BCS), Croplife America (CLA), and

the Chemical Producers and Distributors Association (CPDA)) agreed with EPA's proposal to allow a EDSP test order recipient for the second list to comply with an EDSP test order by ceasing all manufacturing of the listed chemical, because former manufacturers will not receive any new income from the chemical to pay for the new EDSP testing requirement and language in the statute refers to manufacture and production in the present tense. The San Francisco REACH Team (SFRT) requested that EPA's EDSP test order procedures be revised to include a clear timeline for when the production must cease.

EPA intends to allow a SDWA EDSP test order recipient for the second list to comply with the test order by ceasing all manufacturing, including manufacturing for export only, and importing of the listed chemical. EPA considers this approach to be consistent with the language of the statute and with the decision to accept pesticide cancellation as an acceptable response to an EDSP test order issued under FIFRA. EPA will require recipients to provide a timeline for the cessation of production as part of the explanation and documentation supporting the claim. Rather than specifying a single timeline, the Agency will take individual circumstances into account, essentially using the same procedure it applies to accepting pesticide cancellations as an acceptable response to an EDSP test order on a pesticide active ingredient.

The American Water Works Association (AWWA) commented that an EDSP test order recipient should not be allowed to respond by ceasing manufacture, observing that this would not absolve them from having contributed to the presence of the chemical in the environment, and that it might persist in the environment.

While the comment has merit, EPA has decided that, in this instance, the equities weigh in favor of allowing companies to satisfy the order by entirely ceasing to manufacture the chemical. As discussed in the draft SDWA/FFDCA policies and procedures (Ref. 5), a number of considerations weigh against requiring manufacturers who choose to cease manufacture of the chemical to nevertheless conduct EDSP testing. Specifically, if an EDSP test order recipient stops manufacturing and importing a chemical, it will ultimately lead to less exposure to the chemical in sources of drinking water. (The decline will happen at different rates, depending on the chemical and whether the chemical is found in surface water or ground water.) Moreover, an order recipient who ceases to manufacture or import a chemical that is subject to EDSP testing will no longer receive any economic benefit from the sale of the chemical with which to defray the cost of testing. This approach will effectively focus the costs on those companies that can best bear the costs of testing. Further, as discussed in this unit, EPA has been unable to develop an effective mechanism for issuing EDSP test orders to past registrants, manufacturers, and importers given the practical, legal, and equitable difficulties of identifying and assessing the contributions of past participants. However, if EPA is unable to obtain information on most chemicals for which there is continued and ongoing significant exposures, EPA may revisit the issue.

B. Persistence

EPA sought comment on whether, and how, to factor chemical persistence into EDSP policies and procedures to account for the contribution associated with past registrants, manufacturers and importers, to the presence of a chemical in a source of

drinking water, given that the Agency's policy has been to only issue orders to current registrants, manufacturers, and importers.

Multiple commenters (API, People for the Ethical Treatment of Animals (PETA) and the Physicians Committee for Responsible Medicine (PCRM), ACC, BCS, and CLA and the Endocrine Policy Forum (EPF)) indicated that EPA should not consider a chemical's persistence in the environment when implementing EDSP, noting among other things that "persistence" does not appear in the language of the FFDCA and asserting that it is subject to differing interpretations. Commenters observed that the issue of persistence is most likely to arise only for chemicals that have not been manufactured and used by anyone for a significant period of time (i.e., "legacy chemicals"). Some commenters observed EPA would have to develop a legal and equitable process for identifying those chemicals along with all past manufacturers and importers, many of whom may not have manufactured or imported the chemical for decades.

Two commenters (SFRT and AWWA) advocated that EPA should hold accountable all past registrants, manufacturers, and importers that have contributed to health and environmental impacts from past production activities, even if they are no longer actively manufacturing or importing a particular chemical, because chemicals persist in the environment, the consequences often become apparent decades after the cessation of exposure to a chemical, and companies should share the cost of generating data.

Under SDWA, EPA issues an EDSP test order based upon a finding that a chemical "may be found in sources of drinking water" and "that a substantial population may be exposed." While EPA believes that persistence can be defined (persistence is a

factor in a variety of EPA's water and toxics programs; e.g., 40 CFR 125.122, 141.24, 711.6, 792.3, 795.70, 796.1050, 798.2250, and 799.5075), SDWA does not explicitly address how to factor in the possible presence of a chemical in a source of drinking water from past manufacturing and importing. And, although, EPA believes that the potential long term impacts of a persistent chemical in sources of drinking water is an important consideration, EPA has not been able to develop an effective mechanism for issuing EDSP test orders to past registrants, manufacturers, and importers given the practical, legal, and equitable difficulties of identifying and assessing the contributions of past participants. Accordingly, EPA does not intend at this time to issue test orders to entities other than current registrants, manufacturers, and importers.

For more information on how EPA addresses commenters' concerns about chemical persistence, see the comment response document for the second list of chemicals (Ref. 7).

C. Catch-up Orders and Data Compensation

EPA sought comment on "whether 5 years is the appropriate length of time that the Agency should continue to issue SDWA/FFDCA catch-up orders as a means to ensure equitable sharing of test costs." (Five years is the length of time that data compensation is available for test rules issued under TSCA section 4. (See 40 CFR part 791.))

The Methanol Institute argued that SDWA chemicals should be entitled to the same 15-year compensation period as pesticide chemicals, stating there was no logical reason to distinguish between SDWA chemicals and pesticide chemicals since both categories of chemicals are being subjected to the same testing requirements pursuant to

the same legislative enactment. The SFRT and the ACC took similar positions. In addition, the 15-year compensation period applies to industrial chemicals used as inerts in pesticides as well.

After carefully considering these comments and the equities involved, EPA has concluded that the most appropriate length of time to issue SDWA/FFDCA catch-up orders is in fact the same 15-year compensation period as for active and inert pesticide chemicals because it will provide a consistent standard across the entire EDSP. Neither SDWA nor the FFDCA authorized EPA to identify manufacturers or importers of SDWA chemicals through mandatory registration provisions, such as those that apply to pesticide registrants. Furthermore, an inconsistency would develop if SDWA chemicals are not entitled to the same 15-year compensation period as the first list of chemicals, pesticides, particularly if they are mandated to the same testing requirements pursuant to the same legislative enactments.

D. Orphan Chemicals

EPA sought comment on the mechanisms available for testing chemicals for which EDSP test orders do not generate the necessary data.

AWWA asserted that water utilities are not manufacturers that can be required to test under FIFRA or TSCA, so disinfection byproducts and arsenic and other naturally occurring chemicals should be considered orphan chemicals and EPA should screen and test those chemicals itself.

The BCS, PETA, and PCRM interpreted orphan chemicals as those chemicals no longer being produced or imported and reasoned that as environmental exposures to such chemicals would decrease over time, testing of such chemicals should not be required and

resources to conduct testing should not be expended either by private parties or by the Agency without a documented rationale for why potentially harmful endocrine effects might be anticipated.

Exposure to chemicals that are no longer being produced or imported may not decrease over time if the chemicals occur naturally or are persistent and bioaccumulative. However, exposure also will not increase from any continuing manmade contribution to environmental loading. As discussed in Unit V.A., EPA has not been able to develop an effective mechanism for issuing EDSP test orders to past registrants, manufacturers, and importers, and has, therefore, concluded not to issue test orders for chemicals that are no longer being manufactured or imported (see Unit V.B.). In addition, without reaching any conclusion with respect to whether water utilities can ever be manufacturers, EPA has not sought to require the testing of disinfection byproducts and arsenic or other naturally occurring chemicals as part of this second list of chemicals, but this issue warrants additional consideration.

E. Electronic Notification

EPA sought comment on whether companies that already have a Central Data Exchange (CDX) account with EPA would prefer to receive an EDSP notification electronically as opposed to notification by means of the U.S. Postal Service, either as a standard procedure or by request, and on mechanisms by which EPA could accurately document the receipt of orders through electronic reporting mechanisms.

API commented that it generally supported electronic reporting but, for EDSP, recommended that electronic notification be optional, since there have been technical problems with electronic reporting in other EPA programs.

Electronic reporting has become the standard mode of operation in business and government and provides overwhelming advantages over paper submissions. The OPPT's premanufacture notice (PMN) and Chemical Data Reporting (CDR) rules (formerly known as the Inventory Update Reporting (IUR) rule) already require use of the Internet to electronically report. OPPT has also proposed additional electronic reporting requirements (Ref. 8).

Electronic reporting requires use of EPA's CDX, the point of entry on the Environmental Information Exchange Network for environmental data submissions to the Agency. Currently, CDX has provided stakeholders with the ability to:

1. Submit data through one centralized point of access and fill out a single electronic form which can be submitted instantaneously instead of mailing multiple paper forms.
2. Receive Agency confirmation when submissions are received.
3. Reduce costs associated with submitting and processing data submissions.
4. Pay fees through <https://www.pay.gov>.
5. Utilize publishing services to share information collected by EPA with other stakeholders.

In an effort to streamline the reporting process, reduce the administrative costs, and maintain consistency with other electronic reporting of information submissions and recordkeeping (Ref. 8), EPA will require EDSP test order information to be submitted electronically. EPA will continue to issue EDSP test orders by U.S. Postal Service for the second list of chemicals.

F. Identification of EDSP Test Order Recipients

Though EPA did not specifically request comment on the identification of EDSP test order recipients, some comments were received.

API agreed with EPA that the CDR rule is the appropriate source for identifying current chemical manufacturers and importers, but recommended that EPA only use the Toxics Release Inventory (TRI) as a last resort, because TRI was less specific. AWWA commented that EPA should clarify what entities the EDSP test orders apply to by defining all terms describing potentially affected entities. The ACC commented that EPA should pay close attention to manufacturing and other activities that contribute to the occurrence of chemicals in drinking water to which a substantial population may be exposed, with an emphasis on the equitable sharing of the cost of testing.

EPA believes it is “important to identify and issue orders to all significant manufacturers and importers of a listed chemical” and the Agency intends to rely on the CDR rule, which periodically requires manufacturers and importers to report chemical production information to EPA for chemicals manufactured (including imported) in amounts of 25,000 lb or more at a single site. EPA considers the CDR rule to be a reliable means of identifying manufacturers and importers of non-pesticide, industrial chemicals and believes that the CDR rule generally accounts for most of such chemicals in commerce. EPA intends to use other, publicly available databases, such as, but not limited to, TRI, to identify possible EDSP test order recipients. EPA disagrees that the TRI data are imprecise. TRI data are reported annually and reporters must indicate if they manufacture, including import, a listed chemical as well as more specific information on the manufacture of the chemical. EPA is aware that any given database, including CDR and TRI, is imperfect and has limitations. On the whole, however, EPA believes that

CDR and TRI constitute comprehensive and generally reliable databases. Moreover, no commenter disagreed with EPA's assessment or submitted any information to rebut EPA's conclusions.

In addition, EPA believes that relying on these databases effectively addresses the AWWA request that EPA clarify the entities that will be subject to EDSP test orders, and for a definition of all terms describing potentially affected entities. The rules that establish the reporting requirements for these databases (40 CFR parts 372 and 711) already include definitions of all of the necessary terms and should be already familiar to the regulated community. Nonetheless, EPA asked for, and continues to be interested in learning about, any other credible source or method that may be used to identify EDSP test order recipients. In the final analysis, the objective is to identify responsible manufacturers and importers of relevant chemicals, and not to apportion responsibility. EDSP test order recipients may combine in consortia to conduct the required testing on whatever basis they find most suitable.

SFRT asked that EPA "incorporate a system which takes into account the location of chemical manufacturers and potential disproportionate burden on neighboring communities, in addition to production volume, when issuing test orders" in order to "account for the unequal geographic distribution of manufacturing locations of these chemicals and the potential impact of neighboring communities from a chemical's presence in the drinking water among other sources." SFRT also recommended that, in order to "avoid disproportionate burdens and promote equitable responsibility among manufacturers," EPA issue EDSP test order to "all manufacturers of listed chemicals...

with the exception of manufacturers using small quantities of the listed chemical (reported in grams instead of lbs.) for research and development purposes only.”

EPA believes it is “important to identify and issue orders to all significant manufacturers and importers of a listed chemical.” The Agency intends to rely on the CDR rule, as well as TRI, both of which periodically require manufacturers and importers to report chemical production information to EPA for chemicals manufactured (including imported) in amounts of 25,000 lb or more at a single site. EPA considers the CDR rule to be the most reliable means of identifying “significant” manufacturers and importers of non-pesticide, industrial chemicals and believes that the CDR rule generally accounts for most of such chemicals in commerce. It is unclear what the commenter intends by requesting that EPA require self-disclosure in this context, as the only vehicle for requirements relating to EDSP testing in this context will be the EDSP test orders, and EPA can only issue the orders to those manufacturers it can identify. Nonetheless, EPA is interested in finding other existing sources for reliably identifying EDSP test order recipients and will consider issuing EDSP test orders to other significant manufacturers and importers that are identified. EPA, however, does not intend to issue test orders to companies that only manufacture and/or import a chemical in small amounts for research and development or in amounts more appropriately measured in grams rather than thousands of pounds. Issuing EDSP test orders based on the geographic distribution of manufacturing locations and potential impact of chemicals on neighboring communities is, at least, not an express part of the basic requirement that EPA identify and issue EDSP test orders to chemical manufacturers and importers and would add another complex and potentially burdensome requirement to the issuance of EDSP test orders that appears

unnecessary and unlikely to achieve the primary goal of the program: To obtain the necessary data to evaluate the endocrine potential of pesticide chemicals and drinking water contaminants.

G. Other Topics

1. *Cost sharing.* ACC, CLA, EPF, and CPDA stated that EPA had developed a workable data compensation and cost sharing plan and agreed with EPA's decision to issue catch-up orders to require cost sharing by manufacturers and importers who enter the market after initial orders are issued (but suggested that such orders be issued for 10 instead of 5 years), but recommended that EPA develop new procedures in the form of explicit, legally enforceable compensation rights to ensure fair and equitable sharing of test costs.

Section 408(p) of FFDCA only authorizes EPA to create procedures that operate within the confines of existing statutory authority and to develop procedures to facilitate joint data generation. EPA, however, is authorized to determine what actions comply with a FFDCA section 408(p) test order and intends to use this discretion to create strong incentives for companies to jointly volunteer to develop EDSP test data under the circumstances enumerated in Unit VI.G.

2. *Minimizing duplicative testing.* PETA and the PRCM commented that EPA should mandate, and create incentives to form testing consortia.

EPA does not have the authority to compel EDSP test order recipients to join testing consortia to minimize testing, but may develop procedures to facilitate joint data generation. In particular, EPA has the discretion to determine what constitutes compliance with an EDSP test order and can exercise that discretion to allow cost sharing

and the joint electronic submission of data by EDSP test order recipients, in appropriate circumstances, to reduce costs and duplicative testing. EPA intends to continue to list other manufacturers and contact information in each EDSP test order as well as providing such information on the Agency's EDSP website.

3. *CBI*. SFRT commented that EPA should strictly disallow CBI claims. The ACC, CLA, and EPF commented that FFDCA authorized, and EPA should provide, EDSP-specific CBI protection, which was critical to protect industry's legitimate intellectual property interests.

FFDCA does not authorize EPA to either create new rights or to modify existing rights to confidentiality. Rather, FFDCA only directs EPA to apply the confidentiality provisions in existing statutory authorities: FIFRA, the Freedom of Information Act (FOIA), and the Trade Secret Act (TSA), as applicable. SDWA, in particular, only authorizes EPA to apply CBI protection under the TSA. Data submitted to EPA in response to an order issued under SDWA/FFDCA for non-pesticide chemicals, for example, would only have the protections provided under FOIA and TSA.

4. *Adverse effects reporting*. ACC commented that EPA has not, but should, give clear guidance on the significance of positive Tier 1 test results for TSCA section 8(e) and FIFRA section 6(a)(2) reporting purposes.

EPA made a considered decision not to reinterpret the existing requirements for Tier 1 data, nor to otherwise take steps to amend the existing requirements. Rather, EPA referenced the existing regulatory provisions of 40 CFR part 159 and existing interpretations of TSCA section 8(e). In general, EPA does not believe that data from a single Tier 1 assay that provides some evidence that a chemical may have the potential to

interact with the endocrine system necessarily meets the standard for information that must be reported in accordance with FIFRA section 6(a)(2) or TSCA section 8(e) in all cases. In addition, EPA believes that it has not yet accumulated adequate experience with the Tier 1 results to be able to provide general guidance as to the significance of positive results from Tier 1 assays for purposes of the reporting requirements under FIFRA section 6(a)(2) or TSCA section 8(e). Under existing procedures, the determination to report is to be made by the company in the first instance, on a case-by-case basis, taking into account all circumstances, and EPA is not aware of any reason to change that with respect to EDSP data. Accordingly, to the extent that Tier 1 information meets the standards laid out in EPA's regulations (40 CFR part 159), or falls within the categories described in EPA's past statements regarding TSCA section 8(e) (Ref. 9), that information should continue to be reported, consistent with those requirements.

Any information previously submitted to EPA under FIFRA section 6(a)(2), TSCA section 8(c), or TSCA section 8(e) need not be resubmitted to EPA in response to an EDSP test order, because EPA would already have the data.

5. Public availability of information. SFRT commented that the EDSP test data on SDWA chemicals should be made publicly available on EPA's website.

EPA intends to make all non-confidential EDSP data publicly available on the Agency's EDSP website. However, TSA and FOIA may apply and provide some protections against disclosure and it may not be possible to publicly post all available data. Nonetheless, EPA expects that confidential data will be limited, and health and safety data for chemicals on the non-confidential TSCA Chemical Substance Inventory

(TSCA Inventory) of existing chemicals, which all of the SDWA chemicals are, may not be entitled to confidential treatment.

6. *OSRI and Weight-of-Evidence (WoE)*. ACC, CLA, EPF, and CPDA commented that EPA's offer to accept OSRI in lieu of EDSP test data was justified, but that EPA had not clearly articulated a basis for evaluating OSRI. ACC, CLA, EPF, and CPDA also commented that EPA needed to develop meaningful WoE guidelines for assessing voluminous Tier 1 EDSP data to determine whether a chemical interacts with the endocrine system and publish peer reviewed guidance for conducting WoE evaluations.

EPA issued guidance on OSRI for Tier 1 test orders in 2009 (Ref. 10) and on WoE approach evaluating Tier 1 screening results in 2011 (Ref. 11).

7. *Communications: Consistent use of language and definitions*. API, ACC, CLA, and EPF commented that, given the sensitivity of the issue of endocrine disruption, EPA should be careful to use clear and accurate definitions for all important EDSP terms and to communicate clearly, accurately, and consistently to the public and within the Agency in order to avoid confusion and misunderstanding.

EPA generally agrees with these comments and has made every effort to be as clear, concise, and unambiguous as possible. EPA has, for example, generally adhered to widely accepted definitions, such as the World Health Organization's (WHO) definition of "endocrine disruptor" as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism" (Ref. 12). EPA has also repeatedly cautioned that the public should not presume that the listing of a chemical or substance indicates in any way that EPA

currently suspects that such chemical or substance interferes with the endocrine systems of humans or other species. EPA plans on maintaining these communications in future EDSP documents. See also EPA's response to comments documents (Refs. 7 and 13).

8. *Schedule.* API, SFRT, ACC, BCS, CLA, EPF, and CPDA commented that EPA should not issue EDSP orders for the second list of chemicals or for Tier 2 testing until the data from the first list had been evaluated and the Tier 1 assays had been examined in light of those data.

The Agency intends to complete review of the Tier 1 data from the EDSP test orders issued for the first list of EDSP chemicals before issuing Tier 1 test orders for the second list of EDSP chemicals. EPA intends to continue to rely on the available validated methods and to follow the recommendations in the 1999 report from the joint meeting of the Agency's Science Advisory Board (SAB) and FIFRA Scientific Advisory Panel (SAP) (Ref. 14). The steps for this process are described in the EDSP Comprehensive Management Plan issued in 2012 (Ref. 15). With these recommendations, the Agency improves the validating screening and testing methods to develop complete information on chemicals being tested. In continuing with this process of developing efficiency, the Agency does not intend to release any finalized EDSP Tier 1 WoE decisions until the EDSP Tier 2 protocols are available.

9. *Enforcement.* SFRT commented that EPA should enact a system of graduated penalties for noncompliance with testing requirements based on the length of delay in complying with requirements.

EPA agrees that graduated penalties are generally appropriate, and has generally exercised its discretion consistent with that policy. For non-pesticides, failure to comply

with an EDSP order carries the same civil and criminal penalties set out in TSCA section 16, under which each new day of continued noncompliance is another violation, so graduated penalties based on the length of delay are already built into the law. For pesticide chemicals, the FFDCA imposes more specific requirements with respect to the penalty for non-compliance, although they are generally consistent with the concept that penalties should be tied to the period of non-compliance. FFDCA section 408(p)(5)(C) requires the suspension of the pesticide registration for the period of non-compliance, and specifies that the suspension shall be terminated upon a determination that the registrant is no longer out of compliance.

10. *Other comments.* EPA also received comments on topics that do not address aspects of the policies and procedures for issuing EDSP test orders, e.g., the use of SDWA authority to issue orders, the basis of SDWA chemical selection, and the second list of chemicals. The comments related to SDWA and the second list of chemicals are addressed in EPA's response to comments document prepared for the second list of chemicals (Ref. 7).

VI. Final Procedures for EDSP Tier 1 Screening Pursuant to SDWA

For purposes of discussing the EDSP policies and procedures in this document, SDWA chemicals can be described as either currently registered PAIs (SDWA PAIs) or "Other SDWA Chemicals" (including inert ingredients in currently registered pesticide products). EPA generally intends to issue FIFRA/FFDCA orders to manufacturers and registrants of PAIs, but would retain the discretion to issue an SDWA/FFDCA test order to any chemical that meets the statutory criteria in SDWA section 1457. Consequently, for any pesticide chemical that also has non-pesticidal uses, in the event that no

FIFRA/FFDCA test order recipient generates the required data because all order recipients opt out of the pesticide market, EPA may decide to issue EDSP testing orders based on the SDWA authority in order to obtain the data. In such instances, the policies and procedures outlined in this document would be applicable.

By contrast, for SDWA chemicals that are not PAIs, (i.e., “Other SDWA Chemicals”), EPA generally intends to rely on SDWA section 1457 and/or FFDCA section 408(p)(5) to issue EDSP test orders. The Other SDWA Chemicals are very similar to the non-food use inert ingredients discussed in the FIFRA/FFDCA policies and procedures (Ref. 1), and the similarities are reflected in the policies that EPA has adopted in this document. Unit VI. describes the policies and procedures that relate to EDSP test orders issued under SDWA/FFDCA authority.

A. Who Would Receive EDSP Test Orders on SDWA Chemicals?

EPA believes it is important to identify and issue orders to all significant manufacturers and importers of a listed chemical. Under FFDCA section 408(p)(5)(A), EPA “shall issue” EDSP test orders “to a registrant of a substance for which testing is required...or to a person who manufactures or imports a substance for which testing is required...” (21 U.S.C. 346(a)(p)(5)(A)). The process EPA generally intends to use to issue EDSP test orders for SDWA chemicals depends on whether the chemical is a SDWA PAI or an Other SDWA Chemical. A chart depicting the process for issuing EDSP test orders on SDWA chemicals is included in the docket (Ref. 16).

As noted, the Agency generally intends to issue orders under FIFRA/FFDCA for SDWA PAIs, and to rely on the FIFRA/FFDCA policies and procedures (Ref. 1). As described in that document, EPA intends to use internal databases -- principally the

Office of Pesticide Program's Information Network (OPPIN) -- to identify technical registrants with a current pesticide registration containing a SDWA chemical as the active ingredient, and anticipates issuing a FIFRA/FFDCA test order to all identified technical registrants.

For Other SDWA Chemicals, EPA generally intends to rely on information reported to the Agency under the TSCA CDR rule (Ref. 17) and TRI to identify the initial SDWA/FFDCA test order recipients. The CDR rule and TRI require manufacturers and importers of certain chemicals included on the TSCA Inventory to report site and manufacturing information for chemicals manufactured (including imported) in amounts of 25,000 lb. or more at a single site, or, for TRI, other lower thresholds as specified. The Agency believes that this information is an appropriate source for identifying EDSP test order recipients. It has been EPA's experience that relying on companies that have reported to the CDR is the most reliable mechanism for identifying manufacturers and importers of (non-pesticide) industrial chemicals. Such manufacturers and importers are required, by regulation, to report under the CDR rule. Companies that report under the CDR rule generally account for most of a chemical in commerce (therefore, in many instances, these companies can be expected to account for most of a chemical when it is found in drinking water), which is the basis for listing a chemical under SDWA authority (see Unit II.B.). As relatively large manufacturers and importers, EPA also believes that companies reporting under CDR comprise the majority of the volume associated with the chemical; these companies are more likely to be able to afford the cost of EDSP testing than companies manufacturing volumes below the CDR reporting threshold. EPA believes that, in general, these manufacturers are analogous to the technical registrants,

who received orders in the first round of EDSP screening. Finally, using the CDR information to identify order recipients will facilitate joint data development, as reporters for these chemicals are generally publicly known and not numerous.

If there are no companies reporting in response to the CDR rule for a given chemical, EPA intends to use other publicly available databases, such as the TRI, to identify other major EDSP test order recipients. For Other SDWA Chemicals that are regulated or tracked by another agency (e.g., pharmaceuticals by the Food and Drug Administration), EPA may also consult with that agency as appropriate to identify main manufacturers and importers. In addition to using CDR, TRI, and other Federal agency databases, EPA also generally intends to issue orders to manufacturers and importers who are subsequently identified as such. The Agency will follow up on any new information it receives to this effect and issue orders accordingly. EPA, however, does not generally intend at this time to issue orders to companies that manufacture or import a chemical for research and development purposes only, or who otherwise manufacture or import quantities of a chemical that are more appropriately measured in grams (e.g., as impurities, contaminants, or byproducts, which are not expected to be released into the environment in significant amounts).

The Agency intends to issue catch-up orders to manufacturers or importers who begin to manufacture or import an EDSP SDWA chemical within 15 years of the issuance of a SDWA/FFDCA test order. The EDSP SDWA chemical catch-up order process will be similar to the catch-up order process described in the FIFRA/FFDCA policies and procedures (Ref. 1), except that EPA generally expects that the source of information for identifying such manufacturers will primarily come from the public,

because there is no industrial chemical registration process comparable to the pesticide registration process that would provide a mechanism for EPA to independently identify such entities. A recipient of such catch-up orders would have the same options for compliance as an initial order recipient: independently generate the data or participate in the cost sharing by making a good faith offer to participate, if it wishes to rely on data developed or submitted by another recipient or consortium to satisfy its EDSP test order obligation.

If, at the end of this process, all EDSP test order recipients have ceased to manufacture a SDWA chemical without submitting the required data, the Agency generally intends to treat the SDWA chemical as an “orphan.”

B. How Will Recipients of Orders on SDWA Chemicals Be Notified?

Order recipients will receive an EDSP test order in one of two ways: By registered mail or electronically. In addition to the EDSP test order, EPA will send each recipient a packet that contains the instructions, background materials, and sample forms needed to comply electronically with the EDSP test order via CDX or will provide directions as to the location of such materials in an electronic format.

C. How Will the Public Know Who Has Received a Test Order on a SDWA Chemical or Who Has Supplied Data?

EPA intends to provide the list of all EDSP test order recipients on the Agency's EDSP website (Ref. 4). EPA invites the submission of information (with proper substantiation) identifying additional entities -- including entities who manufacture for export only -- who should have received a test order. Commenters could either identify

themselves or another person as additional candidates for the receipt of an EDSP test order.

D. How Will the Agency Minimize Duplicative Testing?

As described in greater detail in this unit, EPA generally intends to continue to rely on its existing procedures to minimize duplicative EDSP testing for SDWA chemicals, including continuing to allow companies to voluntarily develop data jointly, and, as described in Unit VI.G., continuing to apply the policies that facilitate joint data development, as well as to accept OSRI in satisfaction of the order.

In addition, the Agency intends to provide the status of the EDSP test orders, including recipients' responses, on the Agency's EDSP website so that both order recipients and the public can determine the status of responses (see for example Ref. 18). EPA will make such information available to enable test order recipients to identify and join other order recipients to develop the data in response to the order, thereby helping to achieve EPA's goals of minimizing duplicative testing and promoting fair and equitable sharing of EDSP test costs.

E. What are the Potential Responses to Test Orders on SDWA Chemicals?

The options for responding to a SDWA/FFDCA test order are similar to those established in the FIFRA/FFDCA policies and procedures (Ref. 1), except that the option of exiting the pesticide market will not be available. The basis for a SDWA/FFDCA order is that a chemical may be found in sources of drinking water to which a substantial population may be exposed. Exiting any given market (e.g., the pesticide market) is not sufficient if the SDWA chemical is manufactured or imported for other uses because the chemical may still be found in sources of drinking water. If sufficient data on a SDWA

chemical that is a pesticide is not generated in response to a FIFRA/FFDCA order (e.g., all FIFRA/FFDCA order recipients exit the pesticide market), EPA may issue a follow-up SDWA/FFDCA order for such chemicals if they have non-pesticide uses.

EDSP test order recipients provide their initial responses electronically referencing the options on a sample Initial Response Form for Individual Order Recipients (Initial Response Form) (Ref. 19). Response options that EPA anticipates including in SDWA/FFDCA test orders are as follows:

Option 1: *Recipient indicates that it intends to generate data.* If the EDSP test order recipient decides to generate new data for each test specified in the order, the recipient would then comply with the procedures prescribed in the EDSP test order. In general, this option would be identical to the option discussed in the FIFRA/FFDCA policies and procedures (Ref. 1). EPA has not identified any changes that would be necessary to accommodate SDWA chemicals. Data generated and submitted would need to comply with the existing requirements for Good Laboratory Practices (GLP), as applicable. GLPs have been set out both in FIFRA for pesticides in 40 CFR part 160 and for TSCA chemicals in 40 CFR part 792. EDSP test order recipients would need to follow any appropriate GLPs, protocol requirements identified in the EDSP test order, and procedures described in EDSP test orders for submitting the data.

Option 2: *Recipient indicates that it is submitting or citing existing data or OSRI.* The recipient would choose this option to indicate that it is submitting or citing existing data (including data previously submitted to the Agency) that it believes is relevant to one or more of the requests in the test order. The recipient's initial response would include either the data or a reference to the data for each assay specified in the order. In

submitting or citing existing data, the order recipient should follow, as appropriate, relevant format guidelines described in the EDSP test order and provide an explanation of the relevance of the data to the order, including, where appropriate, a cogent and complete rationale for why it believes the information is or is not sufficient to satisfy part or all of the Tier 1 test order.

Data compensation procedures may apply to data previously submitted to the Agency. If the data cited or submitted are from a study that was not conducted exactly as specified in the protocols referenced in the EDSP test order or in accordance with accepted scientific methodology or protocol, including but not limited to those presented in EPA's harmonized test guideline compendium (Ref. 20), the recipient would also identify the deviations from the applicable protocol(s), along with an explanation for the deviations, including an explanation as to why, notwithstanding the deviations, the protocol used for developing the cited or submitted data should still be considered as providing an accepted scientific methodology or protocol, and any other information relevant to a decision to accept the data as satisfaction of the order.

EPA would review any existing relevant information submitted or cited (including OSRI) to determine whether the information is acceptable (e.g., the study was not rejected by the Agency for any reason related to completeness or quality) and satisfies the order. Decisions about whether the information satisfies part or all of the Tier 1 test order will be based on WoE from all relevant information available. The Agency would notify the recipient of its determination.

If the Agency determines that the information cited or submitted as part of the initial response received from an order recipient satisfies the Tier 1 test order the electronic Initial Response Form is the only response required.

If, however, EPA determines that the information cited or submitted as part of the initial response is insufficient to satisfy the Tier 1 test order, in whole or in part, the recipient would still need to satisfy any order requirements EPA had determined had not been met. EPA intends to use a WoE approach as described in the EDSP WoE guidance document (Ref. 11) which takes into account data from the Tier 1 assays and any other scientifically relevant information available, to determine whether the chemical has the potential to interact with the endocrine system. Chemicals that go through Tier 1 screening and are found to have the potential to interact with the estrogen, androgen, or thyroid hormone systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary.

Option 3: *Recipient indicates that it intends to enter (or offer to enter) into an agreement to form a consortium to provide the data.* The recipient may choose to join or form a consortium to share the cost of producing the required data. All participants of the consortium must submit their own electronic Initial Response Form for Individual Order Recipients, providing the name of the party who will be submitting the data on the recipient's behalf.

Under this option, the designated lead for the consortium would complete their Initial Responses electronically (Consortium Response Form) (Ref. 21) for the consortium to provide the primary contact for the consortium, the list of participants, and an indication of the consortium's planned response for each assay, along with

documentation of its formation (such as a copy of the joint agreement or a written statement by all the parties that an agreement exists). The joint agreement to produce the data would not need to specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. The designated lead for the consortium would be responsible for submitting the consortium's initial response and accompanying information to EPA by the due date for the consortium's response, consistent with any mailing instructions indicated in the EDSP test order.

Once the consortium submits the data electronically and EPA has completed its initial review, EPA would notify the contact of the consortium indicating whether the order has been satisfied. If satisfied, such an action would satisfy EDSP test order obligations for each of the consortium participants.

If the consortium fails to submit the data or meet the requirements of the order in a timely and adequate manner, each recipient would be subject to penalties of up to \$37,500 per day, unless the recipient were to commit to submit, and then did submit, the required data by the dates originally specified in the order. The Agency has typically granted very few, if any, time extensions for the submission of EDSP data.

The Agency intends to provide to every EDSP test order recipient a list of the other manufacturers and/or importers (to the extent permitted by confidentiality requirements) that have also received an EDSP order for the specified SDWA chemical. This list would be intended to help order recipients identify other companies with whom they could form agreements to develop data jointly, or otherwise collaborate on a response to satisfy the requirements in the order. If the identity of a company subject to the SDWA/FFDCA test order is claimed as CBI, EPA intends to offer the company an

opportunity to identify an agent who would act on their behalf in all matters relating to the EDSP program. For any company that chooses to designate an agent, the Agency intends to make the name of the agent (instead of the company) public by including it on the list of recipients of SDWA/FFDCA test orders. This name use would be similar to the process used for FIFRA/FFDCA test orders and presented in the FIFRA/FFDCA policies and procedures (Ref. 1). If the identity of a company subject to the EDSP test order is claimed as CBI, and yet the company does not name an agent, that company's ability to obtain data compensation from other parties (or rely on compensable data submitted by other parties) would likely be affected. EPA intends to make available the list of EDSP test order recipients on the Agency's EDSP website (Ref. 4). EPA intends to update the list with subsequent publication(s) and posting(s) as appropriate. For example, the Agency intends to post the status of the EDSP test orders, including the recipient's response, on the Agency's EDSP website so that both EDSP test order recipients and the public can check on the status of responses to the EDSP test orders. This public listing is intended to also facilitate the formation of consortia to develop data jointly since recipients would know all other entities required to generate the same data.

Option 4: *Recipient claims that it is not subject to the EDSP test order.* Under this option, a recipient would claim that it is not subject to the order because it does not manufacture or import the chemical identified for EDSP testing, or because it believes the order was otherwise erroneously sent. This option would be essentially the same as the option discussed in the original policies and procedures for manufacturers of inert ingredients. EPA has not identified any issues unique to SDWA chemicals that would warrant a change in policy on this point. An explanation of the basis for the claim, along

with appropriate information to allow the Agency to substantiate the claim, would accompany the Initial Response. The Agency intends to evaluate the claim and respond to any request within 90 days of receipt. If EPA were unable to verify the claim, the original requirements and deadlines in the order would be expected to remain. If EPA were able to verify the claim, such a response would satisfy the order and no further response would be necessary.

Option 5: *Recipient intends to discontinue the manufacture or import of the chemical.* Under this option, the recipient would indicate it has or is in the process of discontinuing all manufacture and import of the chemical. As noted in Unit V.A., in order to take advantage of this option, a recipient would need to also cease manufacture of the chemical, including for the purposes of export. In addition, the recipient would be required to provide an electronic initial response via CDX that includes a verifiable explanation and documentation supporting its claim. If EPA verifies the claim, the electronic Initial Response Form is all that would be required to satisfy the EDSP test order. If EPA could not verify the claim, the recipient's obligation to comply with the EDSP test order would remain.

Unlike the FIFRA/FFDCA policies and procedures (Ref. 1), which enable a manufacturer or importer of a pesticide inert ingredient to comply with the FIFRA/FFDCA test order by discontinuing the sale of the chemical into the pesticide market, SDWA/FFDCA test orders cannot be satisfied in this manner. A chemical manufacturer or importer that receives a SDWA/FFDCA test order would need to cease all manufacture and import of that chemical. Simply exiting the pesticide market would not address the chemical's potential presence in "sources of drinking water to which a

substantial population may be exposed” and it would therefore be inappropriate to allow companies to satisfy a test order with such a response.

Option 6: *Recipient responds according to one of three other response options.*

As part of the Initial Response, a recipient may also ask EPA to reconsider some or all of the EDSP testing specified in the order if:

a. The recipient can demonstrate (supported by appropriate data) that the chemical is an endocrine disruptor and that additional EDSP Tier 1 screening is unnecessary.

b. The recipient can demonstrate (supported by appropriate data) that the chemical meets the standard for an exemption under FFDCA section 408(p)(4) (i.e., “that the substance is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring estrogen”).

c. The chemical was used by EPA as a “positive control” to validate one or more of the screening assays. In the last data collection, chemicals used by EPA as a “positive control” to validate one or more of the screening assays were only required to submit the assays for which the chemical did not serve as a positive control (e.g., if the chemical served as a positive control in the validation of two assays, the EDSP test order recipient would not be required to generate additional data for those two assays). EPA generally expects that it would continue this policy.

For more information on the response options discussed in this unit, see the FIFRA/FFDCA policies and procedures (Ref. 1).

The Agency intends to make a determination on any claim and respond to the recipient within 90 days of receipt. If EPA cannot verify the claim, the original requirements and deadlines in the order would remain. If EPA were to verify the claim,

EPA would consider the response to fully satisfy the order and no further response would be required.

F. How to Submit Order Responses and Data Electronically?

EPA has developed an electronic submission system for data submitted in response to SDWA/FFDCA test orders following the general process established for TSCA Section 5 Premanufacture Notices and for other TSCA reporting, including TSCA Section 8 CDR. The EDSP order electronic reporting system will allow order recipients to use the Agency's CDX to respond to an order and to submit test data via the Internet. See <http://www.epa.gov/cdx> for additional information about CDX (Ref. 22). If not already registered with CDX, recipients will need to complete a simple registration process in order to use this system for electronic submissions of EDSP test order data, thereby establishing a secure log-on to CDX. Specific requirements associated with these EDSP test orders will be provided directly to the order recipients, and are expected to include:

- Registration with CDX, resulting in the establishment of an electronic signature usable for electronically submitting EDSP test order responses.
- Access to a web-based response form, including the ability to attach PDF files.
- Encrypted submission to EPA via CDX.

Each EDSP test order would contain specific, updated information regarding the most current process to use to respond to the EDSP test order.

G. How Will EPA Facilitate Joint Data Development and Cost Sharing for SDWA Chemicals?

As described in the FIFRA/FFDCA policies and procedures (Ref. 1), the Agency believes that FFDCA section 408(p)(5) does not provide the authority to create requirements for joint data development, including a requirement to use binding arbitration to resolve disputes, as does FIFRA section 3. In EPA's view, FFDCA section 408(p)(5)(B) merely establishes a qualified direction that the Agency "[t]o the extent practicable ... minimize duplicative testing" This, standing alone, does not create new authority to compel companies to use arbitration to resolve disputes arising from an effort to develop data jointly, nor does it even authorize EPA to impose a requirement for joint data development. Rather, EPA believes that this provision directs the Agency to create procedures that operate within the confines of existing statutory authorities. While FFDCA section 408(p) does not allow EPA to impose requirements identical to those authorized by FIFRA section 3, EPA has the authority under FFDCA section 408(p) to develop Agency procedures that would facilitate joint data generation and electronic submission. Specifically, the Agency has discretion to determine what actions constitute compliance with a FFDCA section 408(p) test order, and EPA intends to apply this discretion in a manner that creates strong incentives for companies to voluntarily develop data jointly. Section 408(p) of FFDCA confers adequate discretion for EPA to consider whether a recipient has fulfilled its obligation to provide data when the recipient individually or jointly submits results from the required studies, or when EPA judges that it would be equitable to allow the recipient to rely on, or cite, results of studies submitted by another person.

At the same time, however, each recipient of an order under FFDCA section 408(p) has a separate obligation to satisfy the Tier 1 test order that it received. EPA

thinks that FFDCA section 408(p) confers adequate discretion to consider that a recipient has fulfilled its obligation to provide data when:

- The recipient individually or jointly submits results from the required assays.
- EPA judges that it would be equitable to allow the recipient to rely on, or cite, results of studies submitted by another person.

The determination of whether it would be equitable to allow citation to another recipient's data will be necessarily based on a case-by-case review of the specifics of the individual circumstances. However, the Agency believes that it would generally be equitable to allow a recipient of a FFDCA section 408(p) test order to rely on the results of studies submitted by another person where:

- The data generator has given permission to the recipient to cite the results, or
- Within a reasonable period after receiving the FFDCA section 408(p) test order, the recipient has made an offer to commence negotiations regarding the amount and terms of paying a reasonable share of the cost of testing; has included an offer to resolve any dispute over the recipients' shares of the test costs by submitting the dispute to a neutral third party with authority to bind the parties (e.g., through binding arbitration); and, if arbitration is requested, participates in the arbitration proceeding and complies with the terms of any arbitration award.

The Agency believes this approach to minimizing duplicative EDSP testing, which parallels that used under FIFRA section 3(c)(2)(B), provides all recipients of FFDCA section 408(p) test orders adequate incentives to develop data jointly. In the first instance, where the data generator had granted permission for another party to cite its data, the equities are clear, and EPA has no reason for refusing to allow it. In the second

instance, where the data generator received an offer to commence negotiations regarding the amount and terms of compensation and to go to a neutral decisionmaker with authority to bind the parties failing successful negotiations, EPA believes that the company has demonstrated a good faith effort to develop data jointly, and consequently would typically consider that the order recipient had complied with the order. Based on EPA's experience under FIFRA, there would be little or no reason for a data generator to decline such an offer. Moreover, if EPA did not adopt such an approach, the end result would effectively confer the sort of "exclusive use" property rights established under FIFRA section 3(c)(1)(F), on a broad category of data, and EPA does not believe that FFDCA section 408(p)(5) creates such rights, or provides EPA with the authority to create such rights. These conditions would also apply to recipients of any "catch-up" FFDCA § 408(p) orders, who enter the market after the data have been submitted.

H. What Procedures Can EPA Apply for Handling CBI for SDWA Chemicals?

As stated in the FIFRA/FFDCA policies and procedures (Ref. 1), FFDCA does not authorize EPA to either create new rights or to modify existing rights to confidentiality, but directs the Agency to create procedures that operate within the existing confines of FIFRA, FOIA, and TSA. SDWA has no provisions that authorize EPA to extend protections for handling CBI beyond those established by TSA. Thus data submitted in response to SDWA/FFDCA orders would only be subject to the protections under FOIA and TSA, with the notable exception of data generated on pesticide chemicals. Manufacturers of a food use inert ingredient that is also identified as a SDWA chemical should generally expect to receive SDWA/FFDCA test orders; however, all CBI and data compensation provisions established in FIFRA would still apply. In addition,

under certain circumstances, data generated on non-food use inert ingredients may be entitled to FIFRA CBI and data compensation protections. Test order recipients for the food use-inert, or a pesticide with a food tolerance or exemption, should consult the FIFRA/FFDCA policies and procedures (Ref. 1) for a more detailed explanation of the FIFRA provisions that apply.

The identities of chemicals on the non-confidential portion TSCA Inventory (i.e., the chemical identity of the chemical substance is publicly known), contained in health and safety data subject to TSCA may not be entitled to confidential treatment (Ref. 23). In addition, because the chemical identity is public for all SDWA chemicals on the second EDSP chemical list, EPA expects that there would be no need to claim submitted information as confidential. EPA also believes that it would be particularly difficult to substantiate such a claim, given that the information would already be publicly available.

As described in Unit V.E. under Option 3, when the identity of a company subject to the SDWA/FFDCA test order is claimed as CBI, EPA intends to offer the company an opportunity to identify an agent who would act on their behalf in all matters relating to EDSP. For any company that chooses to designate an agent, the Agency intends to make the name of the agent (instead of the company) public by including it on the list of recipients of SDWA/FFDCA test orders.

I. What is the Process for Contesting a Test Order or Consequences for Failure to Respond or Comply with a Test Order?

EPA generally intends to rely on the existing interpretations and policies relating to pre-enforcement challenges to and enforcement of a test order. Order recipients are encouraged to consult the FIFRA/FFDCA policies and procedures (Ref. 1) for further details on these policies.

J. What is the Informal Administrative Review Procedure?

EPA generally intends to continue to include the informal administrative review provisions in SDWA/FFDCA test orders by which recipients could raise any questions or challenges concerning the issuance of the order, that were included in the orders issued for the first list of chemicals. As explained in the FIFRA/FFDCA policies and procedures (Ref. 1), because the mere filing of the objection (or indeed, the filing of a judicial challenge) would not extend the deadline for submission of the studies, in order for this process to be completed in a timely fashion, EPA expects order recipients who file a challenge to present their objections with sufficient specificity and detail to allow the Agency to effectively evaluate the issue(s) presented. EPA would review the issues presented and respond within a reasonable amount of time. The Agency understands that it will need to respond to such objections within sufficient time for the order recipient to comply with the orders, or to pursue judicial review.

K. What are the Adverse Effects Reporting Requirements?

EPA is not modifying any of its existing reporting requirements or any of the policies with respect to how the adverse effects reporting requirements relate to EDSP data.

Adverse effects reporting requirements for pesticide chemicals in registered products are established in FIFRA section 6(a)(2) and can be found in the FIFRA/FFDCA policies and procedures (Ref. 1). In addition to requirements under FIFRA, TSCA section 8(c) allows EPA to request that companies record, retain and/or report “allegation of significant adverse reactions” to a chemical substance or mixture that the company produces, imports, processes or distributes (15 U.S.C. 2607(c)).

Additional information can be found in 40 CFR part 717. Chemical substance is defined in TSCA (15 U.S.C. 2602(2)).

Under TSCA section 8(e), U.S. chemical manufacturers, importers, processors, and distributors are required to notify EPA within 30 days of new unpublished information regarding their chemical if the information may lead to a conclusion that the chemical poses substantial risk to human health or the environment (15 U.S.C. 2607(e)). “Substantial risk” information is information that offers reasonable support for a conclusion that the subject chemical substance or mixture poses a substantial risk of injury to health or the environment. The information need not, and typically does not, establish conclusively that a substantial risk exists.

Any information that has been previously submitted under FIFRA section 6(a)(2), TSCA section 8(c), or TSCA section 8(e), to the extent the EDSP test order recipient believes that it is responsive to the EDSP test order, need not be resubmitted to satisfy the FFDCA section 408(p) test orders. The EDSP test order recipient need only cite the previously submitted information in lieu of resubmission.

VII. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

Under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993), this policy statement is not considered to be a “significant guidance document” under the terms of the Executive Order because this policy statement does not raise novel legacy or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. As indicated in

this unit, this policy statement only makes a few modifications that are necessary to address procedural differences that apply to SDWA chemicals.

B. Paperwork Reduction Act (PRA)

The information collection requirements described in this document have been submitted to OMB for review under PRA, 44 U.S.C. 3501 *et seq.* Elsewhere in this **Federal Register** issue is a separate document prepared by EPA that announces the availability of the ICR document. The docket ID number for this ICR submission is EPA-HQ-OPPT-2013-0275. An Agency may not concur or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9. As a new ICR, the Agency does not yet have an OMB control number for this information collection activity. Once assigned, EPA will announce the OMB control number for this information collection in the **Federal Register**, and will add it to any related collection instruments or forms used. Burden is defined in 5 CFR 1320.3(b).

VIII. References

As indicated under **ADDRESSES**, a docket has been established for this notice under docket ID number EPA-HQ-OPPT-2007-1080. The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other

documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Endocrine Disruptor Screening Program; Policies and Procedures for Initial Screening; Notice. **Federal Register** (74 FR 17560, April 15, 2009) (FRL-8399-9).

2. EPA. Order Template: “FFDCA §408(p) Order Template for SDWA §1457 Chemicals.” April 15, 2013. Available in Attachment C(3) to the ICR in Docket ID Number EPA-HQ-OPPT-2013-0275.

3. U.S. Congress. House Resolution 2996, H. Rept. 111-180.

4. EPA. Endocrine Disruptor Screening Program website at <http://www.epa.gov/endo>.

5. EPA. Endocrine Disruptor Screening Program; Draft Policies and Procedures for Screening Safe Drinking Water Act Chemicals; Notice. **Federal Register** (75 FR 70558, November 17, 2010) (FRL-8848-9).

6. EPA. Response-to-Comments Document for the Notice on the Endocrine Disruptor Screening Program’s Draft Policies and Procedures for Screening Safe Drinking Water Act Chemicals that published in the **Federal Register** on November 17, 2010 at 75 FR 70558. March 7, 2013.

7. EPA. Comment Response Document for the Second List of Chemicals and Substances for Tier 1 Screening under the Endocrine Disruptor Screening Program (Categorized Public Comments). February 1, 2013. Available in Docket ID Number EPA-HQ-OPPT-2009-0477.

8. EPA. Electronic Reporting Under the Toxic Substances Control Act; Proposed rule. **Federal Register** (77 FR 22707, April 17, 2012) (FRL-9337-5).

9. EPA. TSCA section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance. **Federal Register** (68 FR 33129, June 3, 2003) (FRL-7287-4).

10. EPA. EPA's Approach for Considering Other Scientifically Relevant Information (OSRI) under the Endocrine Disruptor Screening Program (EDSP). March 26, 2009. Document ID Number EPA-HQ-OPPT-2007-1080-0032.

11. EPA. Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing. September 14, 2011. Document ID Number EPA-HQ-OPPT-2010-0877-0021.

12. EPA. Universe of Chemicals and General Validation Principles. November 2012. Available at http://www.epa.gov/endo/pubs/edsp_chemical_universe_and_general_validations_white_paper_11_12.pdf.

13. EPA. Response to Comments on the Public Review Draft of the Information Collection Request (ICR) entitled "Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)." Available in Docket ID Number EPA-HQ-OPPT-2013-0275.

14. EPA. SAB. Review of the EPA's Proposed Environmental Endocrine Disruptor Screening Program; Review of the Endocrine Disruptor Screening Program by a Joint Subcommittee of the Science Advisory Board and Scientific Advisory Panel. July 1999. EPA publication number EPA-SAB-EC-99-013. Available at http://www.epa.gov/endo/pubs/sab_sap_report.pdf.

15. EPA. U.S. Environmental Protection Agency Endocrine Disruptor Screening Program Comprehensive Management Plan. June 2012. Available at <http://www.epa.gov/endo/pubs/EDSP-comprehensive-management-plan.pdf>.
16. EPA. At a Glance: Issuing EDSP Second List Orders. (March 28, 2013).
17. EPA. Chemical Data Reporting website at <http://www.epa.gov/oppt/cdr>.
18. EPA. Status of EDSP Orders/DCIs as of Wednesday, January 2, 2013.
19. EPA. Sample Form: “FFDCA §408(p) Order for SDWA §1457 Chemicals -- Initial Response Form for Individual Order Recipients” (EPA Form No. 6300-06). March 27, 2013. Available in Attachment D(3) to the ICR in Docket ID Number EPA-HQ-OPPT-2013-0275.
20. EPA. OCSPP Harmonized Test Guidelines website at <http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm>.
21. EPA. Sample Form: “FFDCA §408(p) Order for SDWA §1457 Chemicals - Initial Response Form for Consortium” (EPA Form No. 6300-06-C). March 27, 2013. Available in Attachment D(4) to the ICR in Docket ID Number EPA-HQ-OPPT-2013-0275.
22. EPA. Central Data Exchange website at <http://www.epa.gov/cdx>.
23. EPA. Claims of Confidentiality of Certain Chemical Identities Submitted under Section 8(e) of the Toxic Substances Control Act; Notice. **Federal Register** (75 FR 3462, January 21, 2010) (FRL-8807-9).

List of Subjects

Environmental protection, Chemicals, Endocrine disruptors, Pesticides and pests, Safe drinking water, Reporting and recordkeeping.

Dated: May 29, 2013.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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